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Ahmed Abdallah

Royal College of Surgeons in Ireland, ahmedkhier@hotmail.com

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**Implementation of Safe Surgery Saves Lives initiative in
Ahmed-Gasim's Cardiac Center**

Student ID: 9112723

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of the degree of MSc in Quality & Safety in Healthcare Management,

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Abstract

Aim: This paper reports on the implementation of a Safe Surgery Saves Lives, in Ahmed-Gasim's Cardiac Center in 2011 using a change management framework.

Background: Medical errors and incidence of traumatic injuries in surgical care services were recognized as a proportion of the total global burden of disease. Surgical care and procedures can potentially affect the lives of millions of people worldwide. Studies done by WHO found that wrong person, wrong procedure, and wrong site surgery is a preventable adverse event, and defined a core set of minimum standards that can be applied universally across borders and settings, and developed a Surgical Safety Checklist as a tool to ensure safety culture, teamwork, communications, information handoff, patient involvement, and systematic check of processes.

Methods: A Users' Guide to Managing Change in the Health Service Executive, HSE change model with major four phases; initiation, planning, implementation, and mainstreaming, was used to guide the implementation of the Safe Surgery Saves Live Initiative through using the WHO Surgical Safety Checklist in Ahmed-Gasim' Cardiac Center (AGCC).

Results: Implementation of a surgery checklist improved safety culture, memory recall, communication, team work, systematic check process, and decrease medical errors, such as wrong patient, wrong site, and wrong procedure. Implementation of a surgery checklist did not delay cases or increase load of work.

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It is a pleasure to thank those who made this project possible; the leaders, manager, and staff of Ministry of Health, Ahmed-Gasim's Cardiac Center, and to change project team.

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Chapter 1 Introduction

1.1 Introduction

The increasing of healthcare services complexity over the past decade and increasing of coverage has led to a corresponding rise in the number of reported adverse events, defined as unintended injuries caused by medical error rather than the disease process itself (Michel, Quenon, de Sarasqueta, & Scemama, 2004). Good documentation and reporting systems also helped in identifying the size of problem, such as in the famous report of the US Institute of Medicine named “To Err is Human: Building a Safer Health System,” (IOM, 2000). The huge size of reported medical errors led to establishment of patient safety initiative, and formation of World Alliance for Patient Safety. It was identified as a one of the key tasks facing healthcare at the start of the 21st century. This Safety concept implementation has succeeded in ensuring safety in aviation industry a long before (Donaldson, L J, 2007). By focusing attention on this as a public health issue, World Alliance for Patient Safety was recognized the importance of improving the safety of surgery as the second global patient safety challenge (WHO, 2008).

1.2 Rationale for carrying out the change

Medical errors and incidence of traumatic injuries in surgical care services were recognized as a proportion of the total global burden of disease. Surgical care and procedures can potentially affect the lives of millions of people worldwide. Studies done by WHO found that wrong person, wrong procedure, and wrong site surgery is a preventable adverse event, and defined a core set of minimum standards that can be applied universally across borders and settings, and developed a Surgical Safety Checklist as a tool to ensure safety culture, teamwork, communications, information handoff, patient involvement, and check of processes. WHO Alliance for Patient Safety promote applying those standards through the ““Safe Surgery Saves Lives”” program

(WHO, 2008), hopes to create an environment for improving both access to and safety of surgical care.

Safe Surgery Saves Lives program, aims to improve the safety of surgical care. Nevertheless the surgery nowadays is advanced, complicated, and widely practiced in almost all healthcare facilities around the world, and even the advanced invasive procedures such as cardiac surgery have been came in practice in developing countries.

The final goal of the “Safe Surgery Saves Lives” initiative is to improve surgical outcomes for patients regardless of circumstance or environment. By improving processes already in place in operating theatres safety will be enhanced and quality increased without demanding substantial financial investments in health infrastructure (WHO, 2008). The WHO Alliance for Patient Safety designed the initiative to be simple, widely applicable, and measurable regardless of the operative setting to ensure adherence to proven standards of care in all countries. This initiative piloted in eight countries from different WHO regions, economic circumstances and diverse populations of patients, (Hayned, et al., 2009). Hospitals in eight cities around the globe have successfully demonstrated that the use of a simple surgical checklist, developed by WHO, during major operations can lower the incidence of surgery-related deaths and complications by one third. Analysis shows that the rate of major complications following surgery fell from 11% in the baseline period to 7% after introduction of the checklist, a reduction of one third. Inpatient deaths following major operations fell by more than 40% (from 1.5% to 0.8%). It proved applicability, efficiency and effectiveness and It reduced mortality and morbidity in all eight centers (Figure 1), from the high-performing ones to the developing ones (Hayned, et al., 2009). At least half a million deaths per year would be preventable with worldwide effective implementation of the checklist.



Figure 1: Map of Piloted Cities

Derived by this international safety issue, Ahmed-Gasim’s Cardiac Center (AGCC) was selected for implementing the “Safe Surgery Saves Lives” initiative. AGCC provides specialized, high risk and complicated surgical procedures and interventions, where more 400 cardiac operations done annually with 5% mortality rate, and not well documented or analyzed morbidity rate. AGCC managers and staff are looking for excellence and safety of services. They are challenging to be the pioneers in implementing this initiative as a pilot for Khartoum State hospitals. They feel the need to ensure the safety of surgical and invasive procedures. There is more the 35 major cardiac operations performed in AGCC monthly, with 5 % mortality rate and unmeasured poor documented morbidity rate (AGCC , 2011).

1.3 Summary

Safe Surgery Saves live initiative is a part of global patient safety program developed, piloted and evaluated by the WHO 2007 – 2008. The main tool used was the “WHO Surgical Safety

Checklist”. The aim of this program is to ensure surgical safety, and prevent wrong patient, wrong site and wrong procedure. Safe Surgery Saves live initiative as a change project was implemented in Ahmed-Gasim’s Cardiac Center in 2011. I was assigned by health authorities in the Ministry of Health (MOH) as change leader. The quality team was selected to assist the change leader and form the “change project team” responsible for the implementation of “Safe Surgery Saves Lives” project. Project team followed the ‘Users’ Guide to Managing Change in Health Service Executive’ (HSE) change model (HSE, 2008) in the change process. The change project team secured the commitment and participation of the policy makers in the Ministry of Health together with managers of AGCC in the initiation stage, the managers and staff of the AGCC were involved by the change project team and comprehensively participated in planning, implementing and mainstreaming stages. The use of checklist is aiming to improve the team work, safety culture, documentation, recall, and safeguard systematic approach in processes and surgical procedures. The direct and immediate goal of this change project is to improve compliance with minimal set of evidence based standards and decrease medical errors related to human factors.

This paper is composed of five chapters; introduction, literature review, methods, evaluation, and last chapter about discussion and conclusion of this project.

Chapter 2 Literature Review

2.1 Introduction

Search was done in the directories websites of World Health Organization (WHO), patient safety and “Safe Surgery Saves Lives” published document and guidelines, also other health organizations such national patient Safety Agency, and Joint Commission International (JCI) to get the overview of the literature. Which lead to search of the initiative component such as safety culture, checklist, teamwork, communication and other human factors, at last came up to search of implementation of WHO Surgical Safety Checklist.

2.2 Patient safety and safe surgery

Patient safety is a relatively new health care discipline that emphasizes the reporting, analysis, and prevention of medical errors, which often lead to patient harm or adverse health care events. Patient safety as defined by the WHO Alliance is the reduction of risk of unnecessary harm associated with healthcare to an acceptable minimum, which in turn refers to the collective notions of given current knowledge, resources available and the context in which care was delivered weighed against the risk of non-treatment or other treatment (WHO, 2009). And so it is about continuous improvement through building systems and procedures, on evidence learned from medical errors, it is about risk and change management especially cultural change. The problem is well addressed by the landmark Institute of Medicine Report To Err is Human (IOM, 2000), which explore the size of medical errors and questioned the safety of healthcare services and institutes in USA. The size and magnitude of avoidable deaths, injuries and other adverse patient events was not well known until the 1990s, when multiple countries reported shocking numbers of patients harmed and killed by medical errors, classifying that healthcare errors affect ten percent (10 %) of the patients around the world, the World Health Organization calls patient

safety an endemic concern in 2002, WHO Member States agreed on a World Health Assembly resolution on patient safety and launched the World Alliance for Patient Safety in October 2004. The goal was to develop standards for patient safety and assist the countries to improve the safety of health care. The Alliance raises awareness and political commitment to improve the safety of care and facilitates the development of patient safety policy and practice in all WHO Member States. Each year, the Alliance for Patient Safety delivers a number of programs covering systemic and technical aspects to improve patient safety around the world (WHO, 2008).

The resulting patient safety knowledge continually informs improvement efforts such as: applying lessons learned from business and industry, adopting innovative technologies, educating providers and consumers, enhancing error reporting systems, and developing new economic incentives. The safety is basic goal of health care services to accomplish this; health care providers must incorporate safety and quality into their organization to assure appropriate clinical and administrative activities. Over the last decade there has been a growing international recognition that health care facilities are dangerous places and constitute significant threats to the safety of patients (Waring & harrison, 2006).

The shifting away from blaming the individual to building safety into reengineering of processes and systems is a common practice to reduce medical errors. Near misses management proves the vulnerabilities and complexities of health care delivery and the need for a safety systems and standards. Although, to err is human, eliminating “never events” is attainable (Lum & Schachat, 2009).

The WHO Alliance for patient safety published the conceptual framework aims to provide a comprehensive understanding of the area of patient safety definition and program (WHO, 2009).

The framework aims to represent a continuous learning and improvement cycle emphasizing identification of risk, prevention, detection, reduction of risk, incident recovery and system resilience; all of which occur throughout and at any point within the conceptual framework.

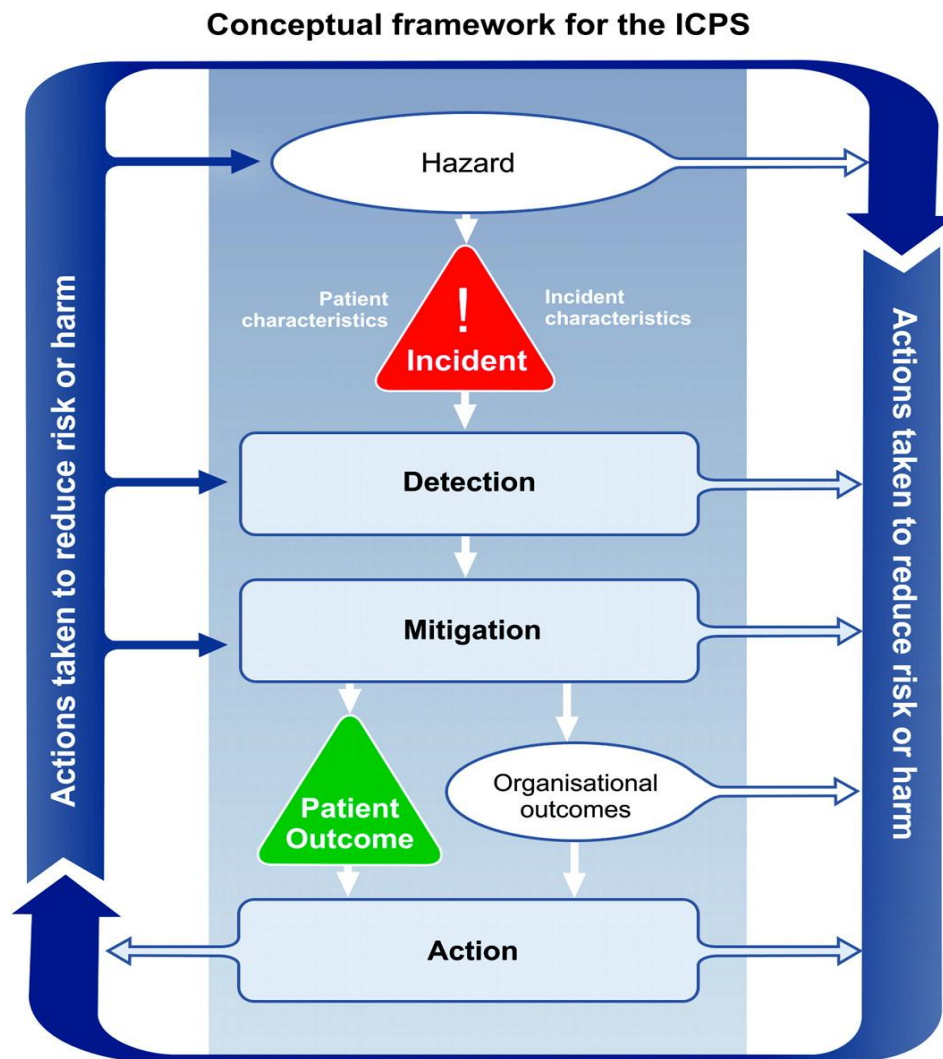


Figure 2: The conceptual framework for the International Classification for Patient Safety

Safety Alliance published ten facts on safe surgery summarized that surgical care and its safe delivery affect the lives of about 7 million patient postoperatively out about 234 million major operations are performed worldwide every year (WHO, 2008). And according to the analysis of

these facts they selected “Safe Surgery Saves Lives” Challenge to be the second goal of Safety Alliance. The aim this initiative is to improve the safety of surgical care around the world by ensuring adherence to proven standards of care in all countries. The expertise developed get benefit of safety approaches in aviation and other high risk industries and developed a checklist (figure 2) as tool to ensure the safety of surgery. They estimate this tool will prevent at least half a million deaths per year with effective implementation of the WHO Surgical Safety Checklist worldwide. These results obtained in the World Health Organization's 2007-2008 pilot study; of its Surgical Safety Checklist and published the initiative of save surgery save lives in 2008 (WHO, 2008).

Surgical Safety Checklist		
World Health Organization		Patient Safety A World Alliance for Safer Health Care
Before induction of anaesthesia (with at least nurse and anaesthetist)	Before skin incision (with nurse, anaesthetist and surgeon)	Before patient leaves operating room (with nurse, anaesthetist and surgeon)
Has the patient confirmed his/her identity, site, procedure, and consent? <input type="checkbox"/> Yes	<input type="checkbox"/> Confirm all team members have introduced themselves by name and role. <input type="checkbox"/> Confirm the patient's name, procedure, and where the incision will be made.	Nurse Verbally Confirms: <input type="checkbox"/> The name of the procedure <input type="checkbox"/> Completion of instrument, sponge and needle counts <input type="checkbox"/> Specimen labelling (read specimen labels aloud, including patient name) <input type="checkbox"/> Whether there are any equipment problems to be addressed
Is the site marked? <input type="checkbox"/> Yes <input type="checkbox"/> Not applicable	Has antibiotic prophylaxis been given within the last 60 minutes? <input type="checkbox"/> Yes <input type="checkbox"/> Not applicable	To Surgeon, Anaesthetist and Nurse: <input type="checkbox"/> What are the key concerns for recovery and management of this patient?
Is the anaesthesia machine and medication check complete? <input type="checkbox"/> Yes	Anticipated Critical Events To Surgeon: <input type="checkbox"/> What are the critical or non-routine steps? <input type="checkbox"/> How long will the case take? <input type="checkbox"/> What is the anticipated blood loss? To Anaesthetist: <input type="checkbox"/> Are there any patient-specific concerns? To Nursing Team: <input type="checkbox"/> Has sterility (including indicator results) been confirmed? <input type="checkbox"/> Are there equipment issues or any concerns?	
Is the pulse oximeter on the patient and functioning? <input type="checkbox"/> Yes	Is essential imaging displayed? <input type="checkbox"/> Yes <input type="checkbox"/> Not applicable	
Does the patient have a: Known allergy? <input type="checkbox"/> No <input type="checkbox"/> Yes Difficult airway or aspiration risk? <input type="checkbox"/> No <input type="checkbox"/> Yes, and equipment/assistance available Risk of >500ml blood loss (7ml/kg in children)? <input type="checkbox"/> No <input type="checkbox"/> Yes, and two IVs/central access and fluids planned		

This checklist is not intended to be comprehensive. Additions and modifications to fit local practice are encouraged.

Revised 1 / 2009

© WHO, 2009

Figure 3: WHO Surgical Safety Checklist

2.3 The checklist

Healthcare relies greatly on healthcare specialists' ability to recall detailed critical information during medical practice. However, memory is likely to be error prone, resulting in medical errors and harm to patients. Many industries, including aviation, factories, operation and maintenance companies and nuclear power, attempted to overcome this particular recall limitation by mandating checklists. After examining flight deck checklists, Degani and Wiener in 1993 identified several advantages regarding effective checklists.

Emerton et al. discussed that the teamwork is definable and measurable and can be improved through formal structured communication, such as checklists. They suggested that their principles could effectively be applied to other high-risk industries, such as healthcare, and surgery in particular (Emerton, Panesar, & Forrest, 2009).

A checklist is a tool widely used nowadays, to ensure documentation. It provides a valuable technique in error management. And checklist is compulsive part of aviation industry and production processes management of factories such as pharmaceutical industries. A checklist can have several objectives, including memory recall, standardization and regulation of processes, procedures or methodologies. Also it provides a framework for supervision of work and evaluations, and a diagnostic tool. Though, in all uses of checklists the central goal is error reduction or best practice adherence (Vijayasekar & Steele, 2009). The origins of the checklist date back to 1935 when a long-range bomber designed by Boeing crashed during a competition. This accident resulted in the death of the most technically gifted pilot on board (Gawande, 2007). A few pilots believed that this catastrophe was a result of a single pilot being forced to remember countless steps before take-off. Consequently, they designed a set of simple step-by-step checks for take-off, flight, landing and taxiing. This resulted in an accumulation of 1.8

million miles without an accident (Gawande , 2007). It is nowadays known that the safety first concept and safety culture concepts are well implemented in aviation industry. Checklists when used in teamwork, have additional benefits and effects such as encouraging communication among teams and stimulating further reform to bring a culture of safety towards patient centered health services (The Lancet, 2008) so the checklist is not an end in itself. Its real value lies in the checklist role in supporting systematic processes, enhancing communication, encouraging teamwork and involvement of patients.

However, the introduction of checklists without adequate training of the team involved may be of no use and could lead to 'checklist fatigue'. It can turn out to be a tick box exercise of no relevance at best, and at worst it can turn out to be a counter-productive exercise. Endangering lives by interfering with the professional judgment and the objectivity of the decision making processes. The operating teams should therefore be given adequate training in the use of these checklists as part of training in non-technical skills and importantly the results of the intervention (either positive or negative) should be fed back to the teams to enhance learning from errors.

2.4 Safety culture and the role of education

Safety culture is a term often used to describe the way in which safety is managed in the workplace, and often reflects "the attitudes, beliefs, perceptions and values that employees share in relation to safety (Cox, 1991). The concept of safety culture originated outside health care, it initiated in organizations that consistently minimize adverse events despite carrying out intrinsically complex and hazardous work, a high commitment to safety at all levels which lead to build a safety culture such as aviation industries, by identifying the high risk activities and areas and the determination to achieve consistently safe operations (Cox, 1991).

Safety culture need a blame free environment where people are able to report errors or near misses without fear, but the high cost of medical errors which may affect lives and health generates individual blame culture in health care, which definitely impairs the progress of a safety culture. One issue is that, while "no blame" is the appropriate for many errors, but certain errors mandate accountability. In an effort to settle the twin needs for no-blame and appropriate accountability, the concept of "just culture" is being introduced (Weiner & Lewis). A just culture focuses on identifying and addressing systems issues that lead individuals to engage in unsafe behaviors, while maintaining individual accountability by establishing zero tolerance for irresponsible behavior. It distinguishes between human error and irresponsible behavior, in contrast to an overarching "no-blame" approach still favored by some. In a just culture, the response to an error or near miss is predicated on the type of behavior associated with the error, and not the severity of the event. For example, irresponsible behavior such as refusing to perform a "time-out" prior to surgery would lead to punitive action, even if patients were not harmed. Although the term just culture can be construed broadly, the term is often more narrowly used to refer to the beliefs, assumptions, and expectations that govern accountability and discipline for unsafe acts (e.g., near misses, medical errors, and adverse events).

Nevertheless safety problem causes and solutions may be outside of the powers of many personnel due to complex systems or procedures which interact in difficult to predict ways leading to a chain of events which results in an injury, and because many are cross-organization (Øvretveit, 2009).

Although illustrating the extent of the shift required in terms of creating a safety culture is a difficult task, but the National Patient Safety Agency – NHS in UK has given advice to

healthcare staff by producing the Seven Steps to Patient Safety guide (NPSA, 2004). The seven steps described are:

- Build a safety culture.
- Lead and support your staff.
- Integrate your risk management activity.
- Promote reporting.
- Involve and communicate with patients and the public.
- Learn and share safety lessons.
- Implement solutions to prevent harm.

To help in safety building WHO published Patient safety curriculum guide for medical schools in 2009. Where the safety problems classified to: (i) the wrong patient in the operating room (OR); (ii) surgery performed on the wrong side or site; (iii) wrong procedure performed; (iv) failure to communicate changes in the patient's condition; (v) disagreements about stopping procedures; and (vi) failure to report errors (WHO, 2009).

Team work, communication and empowerment of staff will help junior doctors or nurses who rarely speak up when they see a senior clinician about to make an error; this is universal and applies to all cultures to varying degrees. However, patient safety principles require that everyone is responsible for patient safety and should speak up even when they are lower in the medical and health-care hierarchy (WHO, 2009).

2.5 Nontechnical skills and human factors

There is growing evidence that poor non-technical skills can be a major cause of error in healthcare. Non-technical skills, or human factors, play an important role in improving team function and improving these skills can drive improvements in patient safety and outcome. This

editorial challenges traditional role stereo-types, and argues that fundamental changes in the behavior of professionals need to be made, and sustained, in order that the whole team can make a valuable contribution to the patient safety agenda (Odell, 2011). He classified human factors in to seven main categories of non-technical skills: 1. Situation awareness. 2. Decision making. 3. Communication. 4. Team working. 5. Leadership. 6. Managing stress. 7. Coping with fatigue.

Communication is considered an integral part of safety (Hohenfellner, 2009), and Milligan discussed the role of education in establishing a culture for patient safety (Milligan, 2007) through studying the too common problem of drug administration errors is used to illustrate the relevance of human factors theory to healthcare education with specific mention made of the Human Factors Analysis and Classification System (HFACS). In this error analysis model preconditions include Environmental Factors, Condition of the Individuals and Personnel Factors (USCG, 2005). Personnel Factors classified to

- 1- Self-Imposed Stress such as; (physical fitness, alcohol, drugs/supplements/self-medication, nutrition, inadequate rest and unreported disqualifying medical condition)
- 2- Coordination/ Communication/Planning Factors; such as crew/team leadership, cross-monitoring performance, task delegation, rank/position authority gradient, assertiveness, communicating critical information, standard/proper terminology, challenge and reply, mission planning, mission briefing, task/mission-in-progress re-planning and miscommunication (USCG, 2005).

Poor intraoperative communication may compromise patient safety, and so Igor Belyansky findings highlighted the importance of communication within the surgical team in the prevention of untoward patient outcomes (Igor Belyansky, 2011). Also Wiegmann et al. highlighted the

nature of many of these work system factors that affect surgical performance including the operating room environment, teamwork and communication, technology and equipment, tasks and workload factors, and organizational variables (Wiegmann, ElBardissi, Parker, & Sundt, 2008).

Braaf et al. in review found documentation performed by healthcare professionals in the perioperative environment, such as surgeons' operation notes, anesthesiologists' records and nurses' perioperative notes, has the potential to result in communication failure and the delivery of suboptimal patient care. Documents such as preoperative checklists have the capacity to be used in coordinating verbal communication of multidisciplinary surgical team members within the perioperative environment, thereby improving patient care (Braaf, Manias, & Riley, 2010)

2.6 Implementation of Safe Surgery initiative

Although it is a few years since the program is published in 2008, the implementation widely achieved in many hospitals and surgical centers worldwide. WHO Patient Safety Alliance continues to support the implementation through publishing training and educational curriculum, brochures, and encourage research in this field (WHO, 2009). Also accreditation bodies produced and updated their standards, and included the safe Surgery goal such Joint Commission International (JCI). They stated in the fourth edition JCI Accreditation Standards for Hospitals; in the international patient goals (IPSG) section (JCI, 2010);

IPSG.1 Identify Patients Correctly

IPSG.2 Improve Effective Communication

IPSG.3 Improve the Safety of High-Alert Medications

IPSG.4 Ensure Correct-Site, Correct-Procedure, Correct-Patient Surgery

IPSG.5 Reduce the Risk of Health Care–Associated Infections.

IPSG.6 Reduce the Risk of Patient Harm Resulting from Falls.

The Implementation of use of the checklist in England & Wales commenced in February 2009 and mandated February 2010. The form was designed for surgery of all types, but it was not appropriate for obstetrics and would not be used effectively. Therefore, modified the peri-operative safety checklist to represent the needs of an obstetric patient more appropriately was designed (Rao, 2010).

The WHO Surgical Safety Checklist provides a systematic approach towards improving team work and reducing the perioperative risk of harm to the patients.

The checklist should be adapted to meet the specific challenges of obstetrics and gynecology” (Burbos & Morris, 2011), also in urology the Surgical Safety Checklist was used successfully in non-cardiac general surgery for patients at least 16 year of age. This success may prompt the European Association of Urology to develop a committee of experts to extend and modify the checklist for urologic surgery (Hohenfellner, 2009).

In survey conducted for all maxillofacial units in the Yorkshire region to determine the use of the WHO checklist, the author found all respondents were aware of the checklist. Only 45% of surgeons were using the checklist. Those not currently using the WHO checklist stated that they were using an alternative form of patient check and most (72%) were using pre- and post-operative team briefings. (Abdel-Galil, 2010).

An interactive analysis identified contextual factors and supportive activities that increase implementation effectiveness. Factors include alignment with institutional and team values, senior leadership, multidisciplinary leadership, internal motivation, physician employment, organizational culture and prior history of quality improvement. Activities include educating and training, facilitating ease of use, valuing staff input, modifying the Checklist for local use,

piloting, framing to promote Checklist use, monitoring and providing feedback (Dante, Gawande, Sara, & Berry, 2010).

Qualitative analysis suggested that effectiveness hinges on the ability of implementation leaders to persuasively explain why and adaptively show how to use the checklist. Coordinated efforts to explain why the checklist is being implemented and extensive education regarding its use resulted in buy-in among surgical staff and thorough checklist use. When implementation leaders did not explain why or show how the checklist should be used, staff neither understood the rationale behind implementation nor were they adequately prepared to use the checklist (Dante , Sara , Lizabeth , William , & Atul , 2011).

“Potential problems on the way to successful implementation of the checklists may be obstructed by difficulties in engaging those individuals who are reluctant to change. Such individuals should be encouraged to participate and shown the benefits to the safety of patients and working practice. The role and responsibility of each member of the surgical team for the completion of the checklist should be clarified. Providing feedback and effective education during the implementation period will help with any unfamiliarity encountered. Regular audits on the implementation of the checklist should be part of the local practice, the results of which should be presented to the staff at regular intervals. (Burbos & Morris, 2011)

But de-Vries found in an observation of 170 surgical procedures, more than 50% of all deviations in surgical processes occurred before or after surgery. Many of these omissions and incidents can and should be corrected at an earlier stage than just before starting surgery, when it could be too late (De-Vries, 2008). So he suggested a checklist that covers the entire surgical pathway from admission to discharge, instead of just the perioperative phase.

Barriers to implementation of the checklist listed by Mahajan Anxiety of unfamiliarity, Hierarchy of staff, Logistics and timing, Duplication, Relevance of checklist, Misuse of the checklist (Mahajan R. P., 2011).

2.7 Summary

The medical errors problem is a real challenge facing the healthcare services. The WHO established the WHO Alliance for Patient Safety to deal with challenge, and find solutions for safety problems. The alliance through The “Safe Surgery Saves Lives” initiative aimed to identify minimum standards of surgical care that can be universally applied across countries and settings. A core set of safety checks was identified in the form of a “WHO Surgical Safety Checklist” that could be used in any operating theatre environment. Each step on the checklist is simple, widely applicable, and measurable, and it has already been demonstrated that its use reduced death and major complications regardless of the healthcare economies it was applied to. The checklist was succeeded to improve safety in many other high risk industries, it ensures systematic check processes, helps recall, enhance communication, encourage teamwork, and patient involvement.

Chapter 3 Methods

3.1 Introduction

The health care services are subject to continuous change leaded with the best practice, international standards, and growing needs and expectations of customers. This change project aim to implement the “Safe Surgery saves lives” through using the modified Safety Surgical checklist (Figure 3) in AGCC, the change process followed the HSE change model.

Surgical Safety Checklist			
World Health Organization		Patient Safety	
Pre - operative	Before induction of anaesthesia (with at least nurse and anaesthetist)	Before skin incision (with nurse, anaesthetist and surgeon)	Before patient leaves operating room (with nurse, anaesthetist and surgeon)
In the clinic <ul style="list-style-type: none"><input type="checkbox"/> 1. The OPD staff verified the correct name of the patient and match with the hospital member<input type="checkbox"/> 2. Detailed clinical notes wrote by the clinician with clear mention of the laterality<input type="checkbox"/> 3. The consent form filled by the surgeon with clear notation of the side, site in addition to the name of the procedure<input type="checkbox"/> 4. the surgeon marked the site of the surgery with a permanent marker<input type="checkbox"/> 5. The anaesthetist clearly noted the procedure, side and site in his notes<input type="checkbox"/> 6. The consent form reconfirmed with the patient or his designated representative in the ward <ul style="list-style-type: none"><input type="checkbox"/> 7. The ward staff verified the correct name of the patient and match with the hospital number<input type="checkbox"/> 8. The ward staff reconfirmed the procedure, side and site with the patient and/or his representative and match with consent form	<ul style="list-style-type: none">Has the patient confirmed his/her identity, site, procedure, and consent?<ul style="list-style-type: none"><input type="checkbox"/> YesIs the site marked?<ul style="list-style-type: none"><input type="checkbox"/> Yes<input type="checkbox"/> Not applicableIs the anaesthesia machine and medication check complete?<ul style="list-style-type: none"><input type="checkbox"/> YesIs the pulse oximeter on the patient and functioning?<ul style="list-style-type: none"><input type="checkbox"/> YesDoes the patient have a:<ul style="list-style-type: none">Known allergy?<ul style="list-style-type: none"><input type="checkbox"/> No<input type="checkbox"/> YesDifficult airway or aspiration risk?<ul style="list-style-type: none"><input type="checkbox"/> No<input type="checkbox"/> Yes, and equipment/assistance availableRisk of >500ml blood loss (7ml/kg in children)?<ul style="list-style-type: none"><input type="checkbox"/> No<input type="checkbox"/> Yes, and two IVs/central access and fluids planned	<ul style="list-style-type: none"><input type="checkbox"/> Confirm all team members have introduced themselves by name and role.<input type="checkbox"/> Confirm the patient's name, procedure, and where the incision will be made.Has antibiotic prophylaxis been given within the last 60 minutes?<ul style="list-style-type: none"><input type="checkbox"/> Yes<input type="checkbox"/> Not applicableAnticipated Critical Events<ul style="list-style-type: none">To Surgeon:<ul style="list-style-type: none"><input type="checkbox"/> What are the critical or non-routine steps?<input type="checkbox"/> How long will the case take?<input type="checkbox"/> What is the anticipated blood loss?To Anaesthetist:<ul style="list-style-type: none"><input type="checkbox"/> Are there any patient-specific concerns?To Nursing Team:<ul style="list-style-type: none"><input type="checkbox"/> Has sterility (including indicator results) been confirmed?<input type="checkbox"/> Are there equipment issues or any concerns?Is essential imaging displayed?<ul style="list-style-type: none"><input type="checkbox"/> Yes<input type="checkbox"/> Not applicable	<ul style="list-style-type: none">Nurse Verbally Confirms:<ul style="list-style-type: none"><input type="checkbox"/> The name of the procedure<input type="checkbox"/> Completion of instrument, sponge and needle counts<input type="checkbox"/> Specimen labelling (read specimen labels aloud, including patient name)<input type="checkbox"/> Whether there are any equipment problems to be addressedTo Surgeon, Anaesthetist and Nurse:<ul style="list-style-type: none"><input type="checkbox"/> What are the key concerns for recovery and management of this patient?

Figure 4: Modified Surgical Safety Checklist

3.2 Change process

The implementation of modified WHO safety surgical in Ahmed-Gasim's Cardiac Center (AGCC) change process is following the recommendation of WHO Alliance for Patient safety. The "Safe Surgery Saves Lives" challenge is guided by three principles of simplicity, wide applicability and measurability. In addition, WHO alliance confirms that the use of this checklist should not take more than two to three minutes. The modified checklist is consisted of four phases; the first phase is included by as adaptation of the "WHO surgical safety checklist" to cover the preparation of the patient from the outpatient clinic and ward, the second phase of the checklist can be done by the anesthetic assistant in the anesthetic room. The third phase or the 'time out' can be done by the operating surgeon before the start of the procedure and the final 'signing out' can be done by the surgeon or the anesthetic assistant.

The change process is mainly about checking the risk areas and orally confirming the processes guided and documented by checklist execution of the following steps in the mentioned four phases (WHO, 2009):

Preoperative phase: it is start with seeing patient in outpatient clinic, the checklist confirm the identification and of correct person, site and procedure by surgeons, anesthesiologists and nurses, confirm the clinical notes is complete, the consent is filled and permanent marker in performed in the operation site.

Sign in phase: Before induction of anesthesia, members of the team (at least the nurse and an anesthesia professional) orally confirm that: The patient has verified his or her identity, the surgical site and procedure, and consent. This will insure the participation of patient and help in prevention of wrong person, wrong site, and wrong procedure; the goal four in JCI standards (JCI, 2010) also confirm orally systematic check and risk assessment.

Time out phase:

Before skin incision, the entire team confirms orally all team members have been introduced by name and role, patient's identity, surgical site, and procedure and systematic review to needed inputs and procedures is done.

Sign out phase

Before the patient leaves the operating room nurse reviews items aloud with the team, name of the procedure as recorded, that the needle, sponge, and instrument counts are complete , That the specimen (if any) is correctly labeled and the surgeon, nurse, and anesthesia professional review aloud the key concerns for the recovery and care of the patient.

The change process also include strengthen of monitoring and evaluation system, so the collection of the checklist and analysis of them is continuous process, to assess the documentation rate, quality, and to measure the compliance of staff with safety practice and attitude. Moreover, these data then have to be correlated with the morbidity and mortality rates of these patients in the hospital, which currently is an entirely separate process to evaluate the impact in long term period.

As a change leader, I chose to use and follow the HSE change model throughout the change process because is developed by medical institute, modern and updated. Also because the HSE change adopted is an organisation development approach which places a strong focus on the people aspects of change such as teamwork, communication, participation and cultural change. It is combined with project management which brings structure and discipline to the process (HSE, 2008).

3.3 Change model

HSE change model (Figure 5) developed by Organisation Development and Design Unit, as a users' guide to managing change, it consists of four main interacted phases; initiation, planning, implementation and mainstreaming and has been developed to improve the experience of patients and service users, help staff and teams play a meaningful role in working together to improve services, promote a consistent approach to change across the system (HSE, 2008). It also fulfilling the effective activities contributing for effective change is motivating change, creating vision for change, developing political support, managing the transition of change and sustaining momentum (Cummings & Worley, 2008). The HSE change model was a result of adaptation of many change models to help change implementation healthcare services (HSE, 2008).

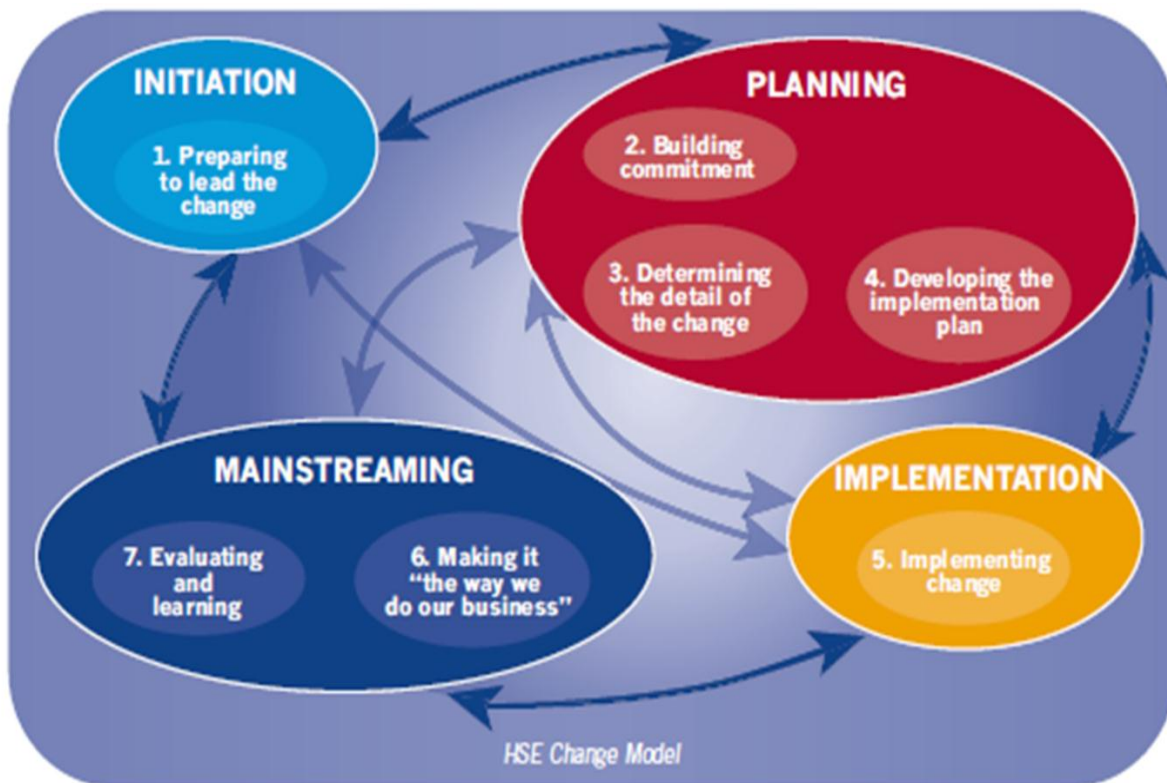


Figure 5: HSE Change Model

3.3.1 Initiation

The purpose of this early preparation and scoping stage is to create readiness and a considered case for change, to establish a sense of shared responsibility, and to scope out a solid foundation for successful change. It builds upon core leadership and management responsibilities (HSE, 2008). It is about getting approval from leaders, and some consultation from experts regarding the applicability and importance of change in the selected area.

In preparing to lead the change I started to communicate the idea of this change the quality managers in the ministry of health in Khartoum state – Sudan, during a training sessions of patient safety where the importance and the need of safe surgery discussed, then I approached the leaders of the ministry, I explained the main objectives, the rationale, and expected results of the project. I found immediate support, and great appreciation, they assigned me as a project leader assisted with the quality team in the ministry of health to start immediately the project. The change project team composed of five members, the team role was to prepare the policy documents to policy makers in the health authorities, and communicate with and AGCC managers and staff, involve them, and ensue their participation and contribution in planning and implementation of the safe surgery initiative change project. The health authority leaders secure the technical support from the WHO office.

Together with quality team we formed the change project team.

In the initiation of the project, the change team performed a meeting, where agreed on criteria of the piloted area, according to that, and out of some alternatives the team agreed to select Ahmed-Gasim's Cardiac Center (AGCC) as a pilot area for implementing the safe surgery saves live project. We consulted the managers of Ahmed-Gasim's Cardiac Center (AGCC) about the applicability of change, and readiness of the AGCC. I met the director general of AGCC and

discussed the project, and get the approval and commitment. Then, I commenced the proposal stage, and I started with the change project team members to perform many formal and informal meetings, and we performed individual contacts in regular meeting with managers and some expertise about approaches and needs for change. The AGCC managers had no resistant but they insisted to have approved policy, detailed plan for implementation, and more resources for their Center. The team prepared the draft policy, and then I performed a meeting with Ministry of Health leaders and get approval of the final policy.

In planning stage the change project team prepared and used power point presentation, brochures, questionnaire, and meeting notes as tools for sharing data, raising awareness, discussion and making decisions. Then, the team executed formal three meetings with AGCC managers and, staff. The team members performed direct contacts and gained consultation for adaption of checklist and collected the baseline data.

The change project clarified leadership roles and identified the key influencers and stakeholders, and this summarized as followed, the acceptance of the leaders of health authorities in Khartoum was gained, and change project leader and team identified, the policy statement for safe surgery prepared, discussed and approved. Then the change project team to start to communicate the change aims with the partners in Ahmed-Gasim's Cardiac Center; managers and surgical services team's leaders. We agreed to Involved them in revising and adapting the tools and determining the preparation needed for the change.

The project team performed two meeting to prepare the needed roles and the skills to enable the change to be successful. The team communicate these rules with the leaders in AGCC and get approval of them, also communicate the skills needed with the AGCC staff in three different groups; the first meeting performed with medical staff in the their weekly clinical morning

meeting, where a surprising event happened, one of five cardiac surgeon was participated in pilot study, when he was in Canada in 2008, the second meeting with nursing staff, and the last one with AGCC quality, infection control, surgical operation managers. Senior managers of the AGCC carried the responsibility for the delivery of improved the safety of services for the cardiac patients, and to be the key change leaders in the system. The AGCC formed a local team responsible for implementation, to work with change project team composed of quality, infection control, surgical operation and nursing managers, and support the management and clinical leaders in the change process. The team members was selected according to their specialty and responsibility,

The change project team identified the stakeholders of this change project in groups because the cardiac health service is a complex, multi-sectorial and multi-professional environment, and assessed the change impacts on them, there was fears increasing the load of work and may document the medical errors of services providers. But on other hands there is definitely positive impact of good reputation of services providers, and good outcomes for patients. For that the support of senior cardiac surgeons, quality coordinator and senior nurses was the most important the change process. Some resistance was expected from some people in the different groups due the lack of knowledge and fears of unknown.

Despite that the health authorities including quality department and Ahmed-Gasim's cardiac center managers have a vested interest in the project success, the voice the senior surgeons has to be heard as the change process is being planned. So interacting with them and their assistant staff is a must for attaining their commitment.

This interaction must give great care for traditional hierarchy of position of seniors of surgeons, anesthesia, and nursing groups. The most appropriate way to communicate and involve them is to direct contact and formal and informal meetings, and consult them in every step.

Although I am implementing this change project in developing country, but fortunately, AGCC is a high class organization with well-educated staff and good resources. Although, it seems that everything is ready, some building capacity, teamwork and communications are badly needed to support people through the change. The internal and external factors support the change, some systems need to improved and developed. Generally, the AGCC culture and the nature of relationships between staff of teams, and the cardiac surgery services support any improvement. Some efforts, motivation and support needed to from leaders to maintain the readiness, and this On other hands being a center for heart surgery this help in accepting best practices and adopting high standards, also dealing with selected well trained staff facilitate the accepting and implementing the change. The perceived risk is allocation of resources

Safe surgery saves live expected to prevent wrong patient, wrong site and surgical procedure through achieving the following objectives and outcomes

- Enhancing safety culture and team work to minimize medical errors
- Patient involvement in safety practice
- Documentation and checklist to eliminate the recall and memorizing limitations
- Improve communications
- Unifying standards and procedures

There is some weaknesses in the quality systems such as poor documentation, using local standards, lack of well trained staff in quality and safety system, health information system,

The change project team designed initial assessment tool adopted from the surgical checklist, all surgical units in AGCC should be involved through their direct participation in meeting and field visits.

Systematic approach of full process will be documented, checked through involving the service providers' team and patient involvement this will expected to improve the safety of service and make a good reputation for the center and specialty and the whole country

The services provision strategy and policy, structure and process, people and culture will be subject for change and improvement. The safety culture, and no blame culture should be improved through team work and learning process from medical errors.

3.3.2 Planning

The purpose of planning phase is to determine the specific detail of the change and to create support for the change process. To communicate the change project with all stakeholders, and build organisation-wide commitment because the broader the support, the easier the process will be. Creating this support ensures that people are joining in a team work, with a clear purpose, intended results and resolve, to create a new future for the organisation (HSE, 2008).

I started advocacy along with change team to the health authorities and AGCC leaders and managers to build commitment and secure the participation of policy makers. And with AGCC senior staff to a sure their participation in adapting the WHO surgical checklist and developing implementation plans, and monitoring and evaluation system. We share the vision of the initiative "Safe Surgery Saves Lives", with safe culture, safety first concepts and learning from errors with all stakeholders. It is widely communicated and discussed with leaders, managers and services providers through formal and informal meetings, posters and trainings sessions. Also the spirit of team work was communicated, discussed and agreed on with services providers.

I reviewed the structure needed for the safe surgery program with change team. We classified needs to; materials such as skin markers, patient identifiers and posters, safety checklists, in addition to short training courses to the staff.

The change leader with quality team performed field visit and conducted interviews with managers and staff and assessed the current situation, SWOT analysis and force field was used (Tague, 2005). The WHO surgical checklist was compared to practice and gap identified, change agents were agreed to be the surgeons, anesthetists, nurses and other assistants, they participated in modification of the checklist by adding the preoperative phase. The results of situation analysis and resources needed reported to the AGCC managers, and training needed reported to quality department, follow up was done, through two formal meeting with each department, ended by approval of required resources and training. The situation analysis revealed that there no checklist used in surgery. And so there are different practices, and no tool to ensure safety of surgery, or enhance teamwork, communication, risk management and systematic check. This identified as gap for improvement.

The WHO Surgical Safety checklist was designed to ensure the minimal required standards for safety of practicing surgery, the WHO checklist was developed to insure teamwork, enhance communication between staff, enforce systematic checking, and securing patient involvement to minimize the human factor in medical errors.

Then the change project team with the participation of AGCC managers and staff developed the detailed implementation plan. And designed the detail of the future state that safety of surgery will be enhanced, though, spreading of safety culture concept, effective communication, team work, patient involvement, and systematic risk assessment. Also processes and procedure of

performing the surgery will continuously adheres to safety rules. The applications of all this standards will surely have positive impact in the final result of the patient management results. In the aspects of decreasing patient harm, morbidity and mortality rates, on the side increases the patient satisfactions and services outcome. This will give the AGCC and its staff an excellence reputation.

All stakeholders agreed on a detailed plan for implementation, consist of adapting the checklist, availing the needed materials, training of staff, and planning the participation and attendance of partners to beginning of implementation, also monitoring and evaluation system was designed and approved.

3.3.3 Implementation

The purpose of implementation stage focuses on implementing and monitoring the change project implementation plan to ensure that it is meeting its purpose. It is vital to signal that the new ways of working are agreed and being implemented, and that inappropriate model of working are discontinued. Leaders must actively attend to what is actually happening in the organisation as it is changing (HSE, 2008).

Step 5: Implementing change

This stage focuses on implementing and monitoring the implementation of safe surgery plan to ensure that it is meeting its purpose. It is vital to signal that the new ways of working are agreed and being implemented, and that inappropriate model of working are discontinued. Leaders actively attended to what is actually happening in the organisation as it is changing (HSE, 2008).

The change implementation started after the policy and implementation plan approved, I started as change leader to communicate with Ahmed-Gasim's cardiac center managers and staff. We

get the approval from director general of Ahmed-Gasim's Cardiac Center. Implementation team was formed in the AGCC involved of quality, safety and surgical operations coordinators. Direct and close contact with the staff was continued to raise their awareness.

The starting date has been specified according to plan discussed and approved with the cardiac surgeons and the senior staff, and in coordination with AGCC leaders. It has been marked as the date at which the first patient undergoing surgical intervention is being subjected to the checking and cross checking procedures.

It has been emphasized on insuring that the intended checking and cross checking steps will not create any sort of disturbance or confusion among the staff, and to avoid patient discomfort as possible. The personal attendance of the change project team was mandated. with the implementation of the program on first group of patient was important as all the proceeding efforts practicality is to be judged be how "smooth" is the steps flow ,as well as to provide some sort of support with the team ,never the less is to detect any obstacle which may arise in order to eliminate it as early as possible .

At the preoperative stage in the clinic it was clearly that the new measures taken complies with previous formerly used ,only that they have been systemized and organized in a manner that favors the issue of the guideline which is the prevention of wrong site ,wrong side ,wrong procedure and wrong person surgery .

At the outpatient department the patient correct name verification along with its match ability with the hospital number were carried out as planned by both the administrative and clinical staff. Some efforts were needed to write the detailed clinical notes as required by the guideline as it was stated that certain standards is to followed, this is the same case for the operation

consent ,as the one previously used did not involve the needed details as required by the guideline. In this aspect continuous communication as well as close working with the staff and patient and their relatives was needed to overcome this obstacle and to bridge the gap creating the needed trust and confidence. This has occurred mainly due the medico-legal responsibilities burden on the staff as the implemented consent required more detailed interventional documentations, a matter which was partially thought to create more constrains on the medical staff. This has been dealt with by more communication, so as to make clear that it is certainly not the aim of the program to create any constrain nor to criminalize health service providers as well as not to unintentionally over protect them at the expense of the patient.

On the other hand the patients were more satisfied with their “empowerment” and involvement in the process of health care giving and never the less by the orientation and enlightenment.

Surgical site marking was another challenge to face, and with our culture in which body exposure lies under the strike umbrella of culture and tradition, skin marking had a wide range of reaction from both; staff (medical and administrative) and patients themselves (along with their relatives). This reaction ranged from complete co-operation to hesitancy and uncertainty from patient and to a lesser extent staff. The medical staff was quite co-operative as the medical background assisted to implement procedure. However, patient and their relatives needed additional efforts as it is always, a new experiment for the patient to undergo surgical intervention. Some patients quite understood and it was easy to do the marking, however, for a minority of them an extra-effort was needed so as to overcome this matter. Most of the hesitated patients had the fear of possible medical impact to the skin marking, and inquired whether it is similar to traditional tattooing or not !, a few were quite reluctant in the acceptance of skin

marking, however there was no absolute refusal by the patient nor by their relatives to the procedure.

For the anesthetic preoperative steps it was somehow challenging as the common practices regarding the preoperative check is done on table, and in most cases a few laboratorial investigations and blood preparation stand for the preoperative anesthetic check!

However, the existing intraoperative checking and documentation system helped much to establish the preoperative practice required by the guideline and the checklist. One of the interesting remarks in this program was that the checking and cross checking helped to create a practice of a non-hierarchy supervision, in which all those involved in the process of surgical patient care giving had the means not only to observe other team member documented performance, but also had an indirect influence to claim to perform any missed procedure by a senior staff through the mandatory cascade of steps and procedure required in the program.

The presence of all supportive documents like X-rays, CT scan, and MRI scan reports confirmation by the surgeon and outpatient staff before transferring the patient to the ward has been carried out by the a delegated medical personnel rather by the surgeons or the anesthesiologists themselves. In the ward the flow of procedure was in general as required as it matches the previously practiced ones.

In the operation reception area although the required procedure flew well, some efforts were needed to specify the responsible medical personnel to do what was needed and how to be responsible for the documentation as the operation reception area consists of multiple staff. The new required procedure for the surgeon to do a preoperative check in the operation reception

area was yet to encouraged as the culture of seeing the operated patient on table at the operation date is still dominating .

An important matter was vital to be considered, which lies in the fact that the surgeon is the leader of the intervening team, as he is responsible for the essential decision of the surgical intervention in the first place, and he is the one performing the main task of it never the less, he is the one to be performed responsible for any degree of failure “if things went wrong”. For that fact it was essential at this stage of implantation were the peak of tension occurs to intervene with the minimum disturbing way and with as much as diplomacy as possible , i.e. ; to sustain the program mainstream keeping the hierarchy of the classical surgical team in mind .

In the operation theater the circulating nurse was the key personnel to assure the guideline and check list procedures flow are accomplished , as he is only free handed team member with the ability to communicate efficiently with all concerning team members , however the presence of the guideline implantation team member was important to guarantee the proper implantation efforts .

Many issues emerged during the early stages of the guideline and check list implementation which was dealt with accordingly, this was expected phases of transition in any change from denial, resistance to exploration to acceptance. As well as the established poor documentation culture and practice. Staff instability yet represent another dragging factor as the continuously rotating staff members and their turn over around the hospital units as well as around different hospitals established the need for continuous efforts in training , coaching and mentoring. However in contrast to the apparently negative impression of the staff turn over the success of the whole program, it represent a positive factor when extending the implementation of this

program to other hospitals as staff familiarity to the program will definitely compensate the time and efforts consumed to overcome the turnover.

The tendency to go back to the old practices was dealt with continuous communication and close working with concerned medical personnel emphasizing on the importance of the new program and its valuable benefits which to all health care stakeholders.

The short term impact of the program was monitored by routine feedbacks ; either personally during the Implementation or through health provider satisfaction forms which the majority of which was in favor of the program , eliciting the need to extend it to cover other aspects of interventions.

3.3.4 Mainstreaming

The purpose of mainstreaming is to focus attention on the success of the change effort and on integrating and sustaining the new ways of working and behaving. This stage also focuses on mechanisms for evaluation and continuous improvement. It is known that the environment in which healthcare operates is constantly changing. The internal dynamics of the organisation will also continue to change. The new reality for people may never feel as if it has arrived (HSE, 2008).

In order to sustain the change and to preserve the momentum generated by this change project, keeping in mind the general behavior, mode of thinking and our national health staff a strategy of short term bullets was adopted as long term projects applicability faces the common obstacle of decrease enthusiasm over time prolongation , An example of these bullets was the involvement of senior managerial, executive and professionals in an orienting ceremonial meeting, other means of incentives were also used as a rewarding act to those taking the burden

of the project. These incentives do not necessary take the form of ‘physical once ‘but rather moral and technical means (training for example) which well have positives impact on the staff career.

Leadership involvement was essential to guarantee the overall commitment to the project, and in order to achieve this it was made clear that the guideline along with the check list provide a solution for a major scope of repeated problem that may drag down his organization and jeopardize his efforts to improve the overall organizational performance and obstruct his / her innovative initiatives

Learning from errors and mistakes was considered as a mean to improve the performance the whole program at both levels of staff and patients and was accomplished by variety of means including; incidence reporting system, focal group discussions, and periodical meetings with prompt implementation of three outputs .

Performance review appeared to be mandatory to sustain the program momentum as it allows us to estimate the qualitative and quantitative outputs as well as to predict the near and far future of the program. Systematic collection the safety surgical checklists, and analysis of them is required for assessment, it can be done by the quality coordinator, and periodic discussions of results of checklist. The integration of the checklist results with the statistical data of mortality and morbidity is highly mandated to evaluate the effectiveness of implementation. On the other hand integrated the training on safe surgery program with the training and capacity building is essential particularly, in nurses and joiner doctors because of their high turnover.

Chapter 4 Evaluation

4.1 Introduction

The plan will include identification of appropriate metrics for both usage and outcome, and ensure reporting to quality and safety department. The usage is continuously monitored and measured, it also short term evaluation to measure the implementation of the safety surgical check list and the degree of compliance of the surgical, anesthesia and nursing staff.

The quality and completeness of checklists also evaluated to measure the knowledge and attitude. On other hand the impact of implementation of the WHO safety surgical checklist on the safety of surgical procedures, in team of minimizing patient harm and decreasing medical errors, need long term evaluation through analyzing the checklist and correlate the result with morbidity and mortality in Ahmed-Gasim's Cardiac Center, also correlated to improvement of safety culture, team work, communication and learning process.

Also the ability of AGCC implementing team assessed to carry on the responsibility for ongoing implementation and monitoring of change is an inherent part of the role of all leaders and managers in the system. It is important, however, the nature of this responsibility to build it into the performance management system within the organisation is not only the role of the leaders.

4.2 Evaluation Tools

For short term objectives evaluation of correct implementation in this change project team approves and used the through participation of the working staff the following for evaluating tools; first, focus group discussion with surgeons and their medical staff, anesthesia and their assistant, nursing staff, and AGCC managers. Second tool was the direct observations from operating room, wards, and outpatient clinics. Third tool was the short two questionnaires for all

medical and nursing staff before and after implementation, and fourth tool was WHO Surgical Safety Checklist review.

For long term impact of the safe surgery program, the change project team recommended researches to cover the areas of expected morbidity, mortality, medical errors, and near misses. Moreover, other researches to cover the changes and improvements expected happened in safety culture, communication, and team work.

4.3 Outcomes of Change

The WHO safety surgical checklist have been implemented in all heart surgical operation rooms and for all types of cardiac surgery operations, the implementation process was institutionalized and integrated to the established systems such as quality and safety, auditing, documentation, supply chain, monitoring and evaluation, capacity building and training systems.

By observation, it was clear that all staff adhere to the new unified standards. One of the worth observation findings is that the team work created in this program helped to deviate the former culture and practices of handling patients partially and as separated “ units” , this is to say that the communication attitude in the new practice in addition to patient empowerment tendency had shifted the fore mentioned patients handling practice to a more humanitarian and integrated one ; this is to say that as an example ; an on table patient used and is being handled by two poorly communicated teams ; surgical and anesthetic teams , resulting in two teams dealing with two parts of one patient with a quite poor communication , a matter which will obviously increase the risk of the undesired adverse events.

I performed the first focus discussion with AGCC staff, they agreed that the 19-item checklist agreed of simplicity and applicability of the checklist, but they mentioned that it needs to be

adopted so as to cover the needed practices in cardiac surgery in AGCC, particularly the preoperative preparation care that occur in the clinic and wards. Some of them particularly two of the surgeons questioned the third criterion of measurability and raised some doubt. In practical application they commented about the importance of quality management system improvement, data management and analysis, training and capacity building, increasing the awareness of patients and availing more resources to support the change.

Using simple and short questionnaire, I conducted a survey about the checklist; most of the staff agreed as shown in figure 6 that the checklist is simple, applicable and takes less than three minutes. Around two third of them agreed that the checklist is measurable. Most of the staff decided that the checklist needs adaptation.

Figure 7 shown most of the staff agreed that the checklist encourage communication, enhanced the teamwork, helped recall, supported the systematic check and enhanced safety.

Almost all staff agreed about the effectiveness of the checklist in creating safety culture and safety practices. This approach of risk assessment in multidisciplinary team was proved effectiveness in other high risk industries such as aviation, factories, and nuclear industries.

In traditional hierarchy the senior inhibit the juniors, and doctors give no chance to other team members.

This leadership skills, management tools, risk management best practice, was brought from other industries to healthcare services such as in the Safe Surgery Saves lives.

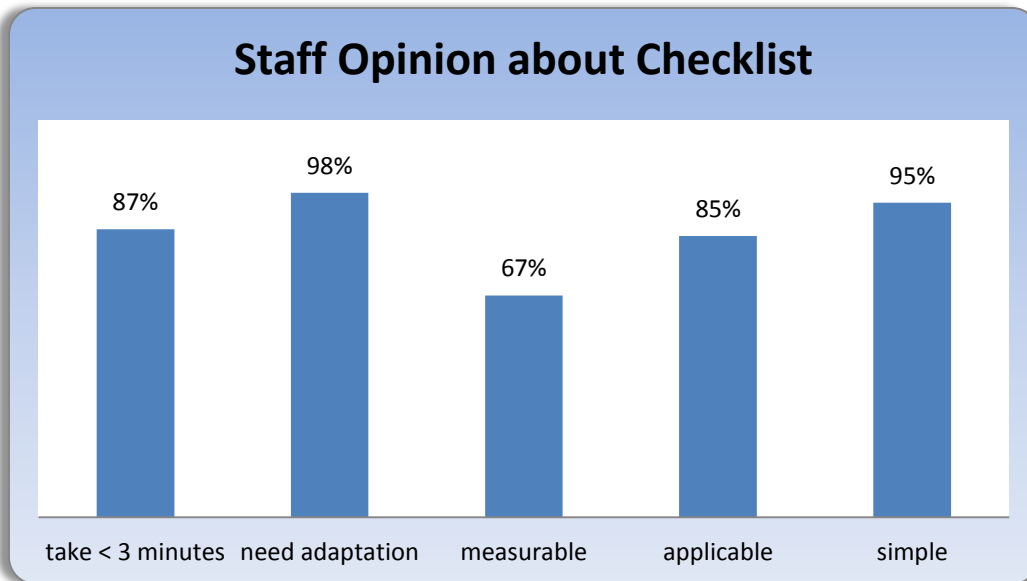


Figure 6: Staff Opinion about checklist

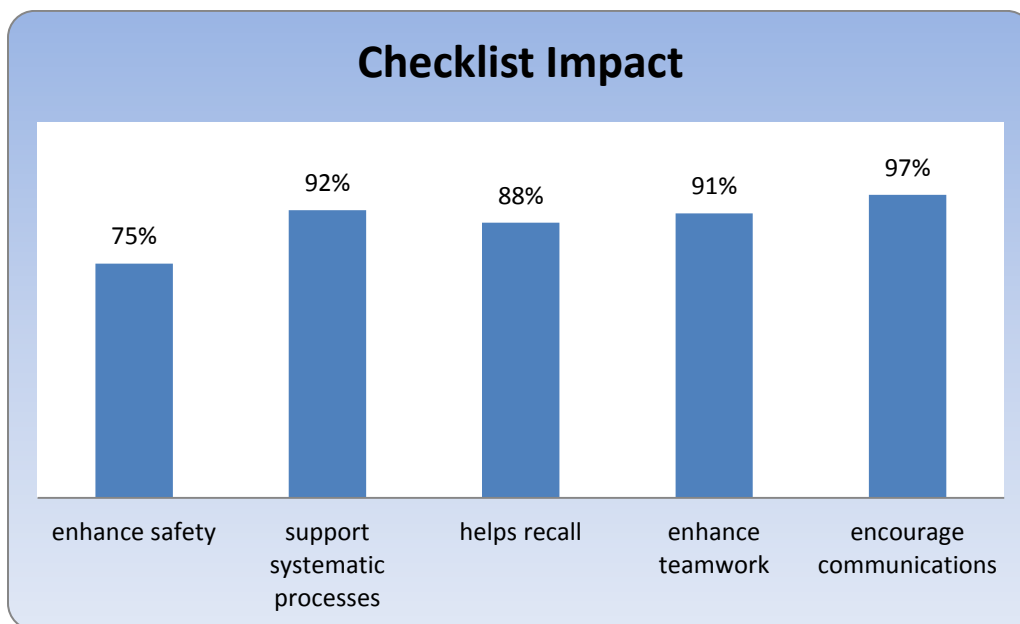


Figure 7: The Checklist implementation impact

4.5. Summary

Despite that AGCC is not accredited hospital by any national or international organization; there are valued local efforts to improve the quality of the services. There is a lot of improvement processes going on. Nevertheless, still there was no previous experience with a well-documented change project or improvement in AGCC.

Generally, the project through extensive uses of quality tools create a new sense, increased the communications, and teamwork culture between the managers and clinical staff. Due to the nature of project itself, the project is introducing new cultures like leadership, management tools, and management practices to the surgery team such as communications, teamwork, risk management, and systematic check with oral confirmation to the rest of team since everything is documented by the checklist. The evaluation of the long term impact such as mortality and morbidity is out of the scope of this paper, but it is recommended to be done later.

The main aim of the project which was implementing the WHO surgical safety checklist was successfully achieved. With regard to the services delivery, the five cardiac surgeons and their staff unified work standards, and stick to the safe surgery saves lives guidelines.

The all participated in designing the change and modifying the checklist. The efforts done in communication with them and other staff eliminated the resistance, reduced the fear from unknown and kept the personal powers as it is. This approach has led to the full involvement of all staff, moreover, the belief that this change is their own work, and has led to appreciating our efforts in initiating and facilitating the change process.

On the management side, the extensive work done in the situation analysis and communication with clinical staff created many improvement projects, and clear the pathways for development.

Chapter 5 Discussion and Conclusion

5.1 Introduction

The HSE change model is enabling continuous and ongoing discussion, evaluation, and interacting phases, throughout the initiation, planning, and implementation and mainstreaming. The results in short term evaluation confirm and support the international experiences with safe surgery initiative implementation.

5.2 Strengths and limitations of the project

The strengths of the project embodied in the nature of it, as it addressing safety in healthcare setting providing a very high risk cases. The attractive vision, global implementation, with evidence based designed tool by WHO expertise, and evaluated outcomes in piloted cities and proved effectiveness. On the side the AGCC as highly specialized center, with the best possible standards in the country, also the highly committed leaders of health authorities in the ministry of Health, and AGCC leaders and managers on all level, this in addition, to cooperative well-educated staff, and fortunately, one of the surgeons participated in the WHO pilot study when he was in Canada 2008.

The major limit of this change project was the time period, where it is not possible to evaluate the long term impact of the Checklist on cardiac surgery in AGCC such as reduction of mortality and morbidity rates, in spite of that the evaluation of the impact is not one of aims of the project to validate the tool because it is already evaluated by WHO pilot study in 2008. Also, limitations of AGCC work systems of quality, chain supply, and training. No functioning reporting system of incidence and near misses, limited used of available technology and paper based medical

records, instability of staff and managers, due to lack of financial motivation and attraction migration, specially nurses and junior doctors.

Also being carried in developing country the resources is to extent represent one of the basic limitation specially in mainstreaming phase, because the trained staff is not motivated and retained used to migrate, on other hand the quality and safety systems need to be improved specially the reporting system of incidence and near misses which need more resources.

5.3 Implications of the Change for Management

This change project with this great contribution of leaders, managers, and senior staff represent a different experience and create new spirit toward safety and quality applications. Extensive use of quality tool, capacity buildings, communication and teamwork establish new culture to the professionals such as cardiac surgeons. The finding of the evaluation confirms the international experiences in the impact of the checklist implementation in creating teamwork, communication, and recall, through systematic check and orally team confirmation.

On the side of service delivery implications, it improved the patient involvement, to ensure the correct person, correct site, and correct procedure. All cardiac surgical units applied the” Safe Surgery Saves Lives” initiative in all heart operations. This resulted in new safety culture, unifying the practice; to best practice, documentation systems strengthening, and reporting system for surgical errors established as a part of patient safety, enforce systemic check for risk area and orally confirmation of main procedures.

5.5 Recommendations for Future Improvements

This project data “the checklist data” should be computerized and connected with the patient medical records and statistical departments. Quality management systems should be strengthened

by improving the reporting system developing such as incidence, near miss events reporting system. Also infection controls program need some improvement. More studies, researches are required to measure the impact of the implementation on the patient morbidity and mortality. Human resources training and retaining should be strengthen.

5.6. Reflections on the Project

Leaded with my beliefs in Jack Welch's quote "If the rate of change on the outside exceeds the rate of change on the inside, then the end is inside". During the implementation of this project I was confident with the idea of the project since it is a best practice developed and evaluated by World Health Organization (WHO). This confidence increased with the nice dealing and respect offered to me by the leaders, manager and staff, and dealing with I as expert and change leader. This greatly helped me to overcome obstacles and expected resistance. Despite all that, I was always thinking about how to fix a change in a changing environment since people, ideas, tools, and resources are always changing.

Second thing that made me worried in the beginning of this project was the fact of implementing this best practice in a developing country, suffering a weak management system and poor resources. But my feeling was completely overturned.

I really surprised with the effect of team work, communication, involvement and participation in eliminating the resistance, and enabling the change to happen. All partners who participated in this change feel the ownership of it. I think this is one of

Day by day, I really rediscovered my country, my people who have a great capacity and good management of resources.

It was the happiest event to find that one of five cardiac surgeons in AGCC had participated in the pilot study in Toronto in Canada. Now he is leading the implementation change among the AGCC staff and acting as a technical advisor for them. He is one of main factors to sustain the change.

Stage 3: Evaluation

Despite that AGCC is not accredited hospital by any national or international organization; there are valued local efforts to improve the quality of the services. There is a lot of improvement processes going on. Nevertheless, still there was no previous experience with a well-documented change project or improvement in AGCC.

Generally, the project through extensive uses of quality tools create a new sense, increased the communications, and teamwork culture between the managers and clinical staff. Due to the nature of project itself, the project is introducing new cultures like leadership, management tools, and management practices to the surgery team such as communications, teamwork, risk management, and systematic check with oral confirmation to the rest of team since everything is documented by the checklist.

The evaluation of the long term impact such as mortality and morbidity is out of the scope of this paper, but it is recommended to be done later.

The main aim of the project which was implementing the WHO surgical safety checklist was successfully achieved.

5.6 Conclusion

The implementation of safe Surgery program in Ahmed-Gasim's Cardiac Center, was succeeded to prove applicability and simplicity. And improved the safe culture in surgery, and put vision to other required improvement In AGCC, and create a functioning team with confidence to apply the future changes, all staff have a positive experience with change management. The expansion of implementation of this project to other hospital and surgical specialties is now in planning stage. The HSE change model is very powerful framework, putting great effort on the initiation phase which lead to the involvement of other partners in planning phase and secure their commitment to the implementation, and mainstreaming phases. It is very suitable for the healthcare services improvement projects.

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